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Free at last

The liberation of six foreign health workers, held without cause in Libya, is to be welcomed. Now Libya should face facts — and clear their names.

The six medical workers held for eight years in a Libyan prison on false charges of deliberately infecting hundreds of children with HIV were finally freed last week. But Libya's cynical insistence on their guilt is casting a pall over this long-awaited event.

Late in the negotiations that saw the medics' sentences commuted from the death penalty to life imprisonment followed by their extradition to Bulgaria, Libya refused a request for the final settlement to state that it did not represent an admission of guilt. When Bulgaria freed the six, Baghdadi Mahmudi, Libya's prime minister, denounced the pardon as a "betrayal", arguing that the medics should have served life sentences. It is time for Libya to end this charade.

The six's only crime was to be in the wrong place at the wrong time. From the outset they were pawns in a larger geopolitical game in which human rights and justice played second fiddle to *Realpolitik* — in this case, Libya's position as a major oil exporter and its utility as an ally in the 'war against terror'. That the medics are out at all is a tribute to the patience and determination of a handful of European diplomats.

An important supporting role was played by scientists who took up the medics' cause, including Nobel laureate Rich Roberts of New England Biolabs; Vittorio Colizzi, an AIDS researcher at Tor Vergata University in Rome; and Luc Montagnier, whose group in Paris discovered HIV. They all persistently dissected the emptiness of the prosecution case, showed multiple avenues of evidence pointing to a hospital infection as the true cause of the outbreak and campaigned tirelessly.

The scientists quickly learned that effectiveness in such matters demanded tight liaison with defence lawyers and human-rights groups. One-off appeals and letters of protest can have some impact in raising public awareness, but effective advocacy requires sustained action, clear objectives and a strategy to achieve them.

When scientists upped the pressure in the run-up to the trial last autumn (see *Nature* **444,** 146; 2006), calling for the scientific evidence to be heard, some observers argued the approach was naive. After all, the court had consistently refused international expertise in the case. But the strategy had already been recognized by the medics' lawyers and human-rights groups as the best card to play.

Had Libya allowed the scientific evidence to be heard in court, the prosecution case would have collapsed. As was always more likely, it refused this, thus exposing the trial as a sham and providing a useful lever for public, and hence political, opinion.

At other times it was necessary for the scientists and human-rights activists to protect the prisoners' interests by showing discretion in their public statements. It was known from diplomatic sources, for example, that Libya's Supreme Court would uphold the death-penalty verdicts — as it did on 11 July — but that these would be commuted soon afterwards. Had there been huge public outrage at the initial verdict, the commuting of the sentences might have been derailed, so those involved agreed that public reaction should be restrained until the final decision.

"The six medics were not given a fair trial and scientific evidence that would have exonerated them was ignored."

Now that the medics are free, such restraint is unnecessary. The 1998 outbreak was a triple tragedy: for the six, for the infected children and for human rights. The six were not given a fair trial, prosecution evidence was fabricated and scientific evidence that would have exonerated the medics was ignored. Their trials were a mockery of justice.

Progressive elements within Libya want this truth to come out. Seif al-Islam Gaddafi, son of Libyan leader Muammar al-Gaddafi, played a significant role in resolving the case through one of his charities. He is convinced that the outbreak was an accident, and wants Libya to face up to its AIDS problem and to promote health care.

Libya has, unfortunately, won plaudits in parts of the Arab world for the way it has played its hand, winning normalization of its political and economic ties with the European Union (EU) and much else besides for releasing the six. The EU and the United States should make further normalization contingent on the Libyan government owning up to the real facts of the case, and exonerating the six. ■

Board games

The way research on human subjects is overseen in the United States requires reform.

There is no greater burden of responsibility for scientists than that placed on those who conduct medical research on human subjects. On the rare occasions that this duty is inappropriately discharged, the results can be devastating. Even so, once the initial outcry dies down, little tends to change.

The diverse collection of institutional review boards (IRBs) that oversee such research in the United States barely qualifies as a 'system'. Despite repeated attempts by the Institute of Medicine and others to highlight their shortfalls, the quality and effectiveness of the boards remain patchy (see page 530).

As committees struggle with heavy caseloads, their ability to monitor ongoing trials is weakened. A large research hospital can process hundreds of applications per year, and gets little help from the federal government. The Office for Human Research Protections oversees thousands of local ethics committees and billions of dollars' worth of clinical research, and operates on an annual budget of just $7 million.

If the US government wanted to strengthen the way human clinical trials are overseen, adequate funding for the Office for Human

Research Protections would be an obvious place to begin. Another improvement would be more widespread accreditation of the IRBs, to help ensure proper training and support for committee members.

But further reforms are also necessary. Some see centralizing the review of multicentre studies as a way of relieving the burden on local review boards. But the debate over whether to centralize, or even regionalize, the review of studies is complex. The United States is a large, diverse and, most of all, litigious country, and local boards help universities to fend off legal action by showing that they have taken responsibility for what goes on within their walls. Nonetheless, centralization deserves to be explored further.

One approach would set up national committees, perhaps run by the National Institutes of Health, that could establish clearer guidelines on the ethical quandaries commonly faced by local review boards. Questions over payments to volunteers, for example, or on what constitutes informed consent, need not all be answered on the current ad hoc basis.

Another challenge facing US authorities is the fact that not all research on human subjects is overseen by the federal government. The IRBs are not federal, but federally funded research on human subjects must be reviewed by them, as must any trial that becomes part of a submission to the Food and Drug Administration. Some states and institutions also require all research on human subjects to be vetted by an IRB. That leaves room for privately funded research to proceed without any requirement for ethical review. It isn't known how much research on human subjects occurs without review by government officials or IRBs. But such research may expose patients to unnecessary risks.

In 1999, the review-board system came under some scrutiny when 18-year-old Jesse Gelsinger died during a gene-therapy trial at the University of Pennsylvania in Philadelphia. In 2001, a healthy woman died after taking an unapproved asthma medication during a clinical trial at Johns Hopkins University. And looking farther afield, in London last year six men became seriously ill during a clinical trial of a monoclonal-antibody therapy.

Overall, it is not a bad record. But that is as much by luck as by design, and if it is to remain the case, real improvements need to be made to the IRB system. The impetus for such change should not have to rely on the bursts of interest that tend to follow mishaps during human trials. ■

A sporting chance

Bans on drug enhancement in sport may go the way of earlier prohibitions on women and remuneration.

Whether you have been following the just-finished Tour de France or waiting for Barry Bonds to break the all-time record for major-league home runs in baseball, the topic of drugs in sport has been hard to avoid of late.

To cheat in a sporting event is a loathsome thing. For as long as the rules of the Tour de France or any sporting event ban the use of performance-enhancing drugs, those who break the rules must be punished whenever possible. But this does not preclude the idea that it may, in time, be necessary to readdress the rules themselves.

As more is learned about how our bodies work, more options become available for altering those workings. To date, most of this alteration has sought to restore function to some sort of baseline. But it is also possible to enhance various functions into the supernormal realm, and the options for this are set to grow ever greater.

The fact that such endeavours will carry risks should not be trivialized. But adults should be allowed to take risks, and experience suggests that they will do so when the benefits on offer are enticing enough. By the end of this century the unenhanced body or mind may well be vanishingly rare.

As this change takes place, we will have to re-examine what we expect of athletes. If spectators are seeking to reset their body mass index through pharmacology, or taking pills that enhance their memory, is it really reasonable that athletes should make do with bodies that have not seen such benefits? The more the public comes to live with the mixed and risk-related benefits of enhancement, the more it will appreciate that allowing such changes need not rob sport of its drama, nor athletes of their need for skill, training, character and dedication.

To change the rules on pharmacological enhancement would not be without precedent. It was once thought that a woman could not epitomize the athletic ideal as a man could, and so should be stopped from trying. Similarly, it was thought proper to keep all payments from some athletes, thus privileging the already wealthy. These prejudices have been left behind, and the rules have changed. As pharmacological enhancement becomes everyday, views of bodily enhancement may evolve sufficiently for sporting rules to change on that, too.

"Is it really reasonable that athletes should make do with bodies that have not been enhanced?"

This transition will not be painless. Some people will undoubtedly harm themselves through the use of enhancements, and there would need to be special protection for children. That said, athletes harm themselves in other forms of training, too. They may harm themselves less with drugs when doctors can be openly involved and masking agents dispensed with.

There is also the problem of who goes first. The first sport to change its rules to allow players to use performance-enhancing drugs will be attacked as a freak show or worse. The same may be true of the second. This may well have the effect — may already be having the effect — of delaying the inevitable.

Perhaps the Tour de France could show the way ahead here. In terms of public respect, endurance cycling has the least to lose and perhaps the most to gain. To be sure, a change in the rules would lead to the claim that 'the cheats have won'. But as no one can convincingly claim that cheats are not winning now, or have not been winning in the past, that claim is not quite the showstopper it might seem to be.

A leadership ready to ride out the outrage might be better for the sport in the long run. If some viewers and advertisers were lost along the way, the Tour could console itself with the thought that it got by with far less commercial interest in days gone by — and that it is more likely to re-establish itself through excellence and honesty than in the penumbra of doubt and cynicism that surrounds it now. ■